

Message

From: Stanley, Darrell [stanley.darrell@epa.gov]
Sent: 5/29/2020 6:02:04 PM
To: Peter Ranslow [pranslow@cermonline.com]
CC: Yan, James [Yan.James@epa.gov]
Subject: FW: PMN-xx-xx32/3
Attachments: Authorization Form for CBI transmittal by e-mail - Signed.pdf

Thanks Peter, my colleague should be contacting you soon with further instructions.

-Darrell

From: pranslow@cermonline.com <pranslow@cermonline.com>
Sent: Friday, May 29, 2020 1:34 PM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

Here is the signed authorization.

Peter

Peter Ranslow, Ph. D.
President, Senior Scientist
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Phone: (207) 837-0102
Fax: (207) 512-1020
www.cermonline.com

From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Friday, May 29, 2020 12:57 PM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Hi Peter,

I just wanted to let you know that the Not Likely Determination Documents for these cases were signed and the company is free to begin manufacture as of today's date. Please sign and return the Authorization form which I sent to you in an earlier email so that we can send you a copy of the signed determinations via email.

Thank you for your effort and patience throughout this review process, I realize that it was probably much more difficult than anticipated.

Please let me know if you have any questions.

Thanks,
Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Thursday, May 21, 2020 7:25 PM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: Re: PMN-xx-xx32/3

It's been submitted.

Peter Ranslow
CERM
207 837-0102

On May 21, 2020, at 3:33 PM, Stanley, Darrell <stanley.darrell@epa.gov> wrote:

Great thanks.

Darrell

From: pranslow@cermonline.com <pranslow@cermonline.com>
Sent: Thursday, May 21, 2020 3:25 PM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

Darrell,

I have completed the upload of new SDSs, etc. to the PMN and it is ready to submit. The PAA is out this week, but will submit it as soon as possible. I will let you know when it is in.

Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Tuesday, May 19, 2020 8:16 AM
To: pranslow@cermonline.com
Subject: RE: PMN-xx-xx32/3

Hi Peter,

Were you able to get a hold of Nicholas regarding the CBI issue?

Also, please let me know when you think you will be able to provide the updated SDS.

Thanks,
-Darrell

From: pranslow@cermonline.com <pranslow@cermonline.com>
Sent: Thursday, May 7, 2020 1:39 PM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

It was a voicemail from I believe Nick Lillo to the technical contact. I don't have a copy.

Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Thursday, May 7, 2020 1:36 PM
To: pranslow@cermonline.com
Subject: RE: PMN-xx-xx32/3

Thanks Peter, I can check into it. Do you have a copy of the communication that you received?

From: pranslow@cermonline.com <pranslow@cermonline.com>
Sent: Thursday, May 7, 2020 10:59 AM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

It is taking longer than anticipated, but should be completed shortly.

Also, there is apparently an issue at EPA with CBI substantiation that we were contacted about, but we haven't been able to get details yet. Any idea what the concerns are?

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Thursday, May 7, 2020 10:53 AM
To: pranslow@cermonline.com
Subject: RE: PMN-xx-xx32/3

Hi Peter,

Just checking in again to see if there has been any progress in getting the SDS revised.

Thanks,
-Darrell

From: pranslow@cermonline.com <pranslow@cermonline.com>
Sent: Tuesday, April 21, 2020 11:23 AM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

Darrell,

Things are taking a bit longer than usual, but we should have it done by the end of the week.

Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Tuesday, April 21, 2020 11:15 AM
To: pranslow@cermonline.com
Subject: RE: PMN-xx-xx32/3

Hi Peter,

Just checking in again to see if there has been any progress on the SDS.

Hope you are well and staying safe,
Darrell

From: pranslow@cermonline.com <pranslow@cermonline.com>
Sent: Monday, April 6, 2020 1:53 PM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

Darrell,

Just wanted to touch based with you that we are working on updating the SDSs and will amend the PMN when we are done. The Covid 19 slowing things down a bit, but we should have this done soon.

IO can authorize another suspension if needed in the meantime.

Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Monday, March 23, 2020 1:16 PM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Hi Peter,

We had been so focused on the respiratory hazard, I forgot to mention that there is one other minor change that we are requesting.

In section 8 of the SDS under 'Hand Protection' could you change 'Wear suitable gloves.' to "Wear gloves impervious to the chemical substance."? It is a small change, but that is the standard language which we prefer.

Thanks,
-Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Thursday, March 19, 2020 3:27 PM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

Darrell,

We felt that based on the hazards identified in the SDS itself and the requirements in place that the 'target organ' wording is redundant and unnecessary. We would propose the following statement for Section 15:

Based on EPA's assessment under TSCA section 5(a)(3), EPA has indicated that this substance may cause skin irritation, eye irritation and potentially also cause respiratory sensitization in rare cases and/or sensitive individuals; those with known allergies to grain or seed dusts are more likely to experience adverse reactions when exposed to this dust and should take additional precautionary measures.

Please let me know if this is acceptable and we will update the SDSs accordingly.

Thanks,
Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Thursday, March 19, 2020 9:45 AM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Hi Peter,

The term "specific target organ toxicity" refers to lung toxicity,. This is primarily based on inhalation of respirable, poorly-soluble particulates and data on nuisance dust. The sensitization hazard is based on inhalation of protein/grain dust.

If you look at section "1.1 Hazard Summary" of the Risk Assessment document that I believe you should have, there is a longer description of the Hazard call.

Let me know if this helps.

Thanks,
-Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Thursday, March 19, 2020 8:54 AM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

Darrell,

Thanks for getting this to us. We are reviewing and looking at options.

One area that they are wondering about is "specific target organ toxicity". They want to clarify exactly what this wording is referring to (i.e. specific effects) and whether or not it would be redundant with the other wording. Can you provide some detail around that?

Thanks,
Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Thursday, March 12, 2020 11:03 AM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Peter,

Thanks for arranging the call. As per the discussion, we have come up with proposed language for section 15 of the SDSs for these PMNs. Please let me know if you are able to make these revisions.

"Based on EPA's assessment under TSCA section 5(a)(3), EPA has indicated that this substance may cause skin irritation, eye irritation, and specific target organ toxicity. The EPA has also determined that, as with many proteinaceous grain dusts, this substance may also cause respiratory sensitization. Those with known allergies to grain or seed dusts are more likely to experience adverse reactions when exposed to this dust and should take additional precautionary measures"

As a reminder, we are only requesting that changes be made to section 15 and that this is not intended to represent a GHS classification.

Thanks,
-Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Tuesday, March 3, 2020 9:24 AM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

Darrell,

You can use the following call in information:

Your UberConference information is below.

Join the call: <https://www.uberconference.com/cerm1>
Optional dial-in number: 207-805-2525
No PIN needed.
International Access Numbers: <https://www.uberconference.com/international>

Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Tuesday, March 3, 2020 9:21 AM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Hi Peter,

I have confirmed that Wednesday 3/11 at 1:00pm will work on our end. I have set up the meeting with two hazard assessors from RAD. Do you have a number that we can call into?

Thanks,
-Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Tuesday, March 3, 2020 8:42 AM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

Darrell,

Thanks for setting this up. 3/11 at 1 Eastern works for us.

Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Monday, March 2, 2020 3:48 PM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Hi Peter,

I've been in contact with both Greg and RAD and I think I should be able to set up a call with some of the RAD health hazard assessors. Would any of the following times work for you:

Wednesday 3/4
10:00
10:30
1:00

Monday 3/9
3:00

Wednesday 3/11
1:00

Please let me know. In the meantime I can continue to put in suspensions for these cases.

Thanks,

Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Tuesday, February 18, 2020 9:08 AM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

I will authorize another suspension. I am available for a call most of this week, with the exception of this afternoon and Thursday afternoon after 2 PM. If it would help, I can contact Greg directly to let him know my concerns, this has gone on for a long time and we would like it to be finalized ASAP.

Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Tuesday, February 18, 2020 9:05 AM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Hi Peter,

I have forwarded your continued concerns to both Greg and RAD. I'm still waiting to hear back regarding when we can do a call. Do you have an idea of when might be a good time for you now that you are back?

I can continue to put in suspensions for these while we continue the review.

Thanks,
-Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Friday, February 7, 2020 9:44 AM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Cc: Jaysen Schock <jaysen_schock@cargill.com>; Tom S. Flynn <Tom.S.Flynn@cargill.com>
Subject: Re: PMN-xx-xx32/3

Darrell,

I will be out of the office next week and am home today due to an ice storm.

At this point we will likely need a conference call with the hazard and risk assessors. I'd also like Greg Schweer on the call.

RADs stance is essentially preempting OSHA and other federal guidance and would unilaterally declare an existing FDA approved GRAS product approved for industrial use around the world without restriction a respiratory sensitized without supporting data. You can pass that statement on to RAD.

Since I will be out and we will likely have to schedule a call after I get back, I will approve another suspension.

Peter Ranslow
CERM
207 837-0102

On Feb 7, 2020, at 9:26 AM, Stanley, Darrell <stanley.darrell@epa.gov> wrote:

Hi Peter,

RAD has reviewed the support document that you provided and revised the risk assessment. Despite the information that you provided, they still can't rule out the respiratory sensitization hazard. If you like, we can have a call to discuss this further and potential pathways forward.

Thanks,
-Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Wednesday, January 29, 2020 11:36 AM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

I approve the suspension.

Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Wednesday, January 29, 2020 11:34 AM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Hi Peter,

Unfortunately there has not been any progress on this. My supervisor contacted the Risk Assessment Division again on 1/17/20 regarding this case, but I haven't heard anything back from them yet.

I can continue to put in the suspensions in the meantime. Sorry I don't have any new information for you.

Thanks,
-Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Wednesday, January 29, 2020 11:08 AM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

Darrell,

Just wondering if there has been any movement on these?

Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Tuesday, January 14, 2020 3:40 PM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Hi Peter,

These cases are still being reviewed by management. I sent them the support document that you provided, I'm not really sure of the timeline for them to complete the review though. I really apologize for how long this is taking.

Please let me know if we can put in the suspensions to allow us to continue the review.

Thanks,
-Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Monday, January 6, 2020 3:06 PM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

Darrell,

The support document I faxed earlier should be submitted through CDX today or tomorrow.

Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Monday, December 23, 2019 9:16 AM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Hi Peter,

No, unfortunately I haven't heard anything new on this case. I can try to check with RAD, but I don't think anything will happen before the end of the year at this point.

I will let you know if I find out anything.

Thanks,
-Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Friday, December 20, 2019 10:33 AM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

Darrell,

Just wanted to check in and see if you had heard anything more about this?

Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Tuesday, December 10, 2019 4:00 PM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Received. I will pass this on to RAD and keep you posted.

Thanks,
-Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Tuesday, December 10, 2019 3:46 PM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

It was sent.

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Tuesday, December 10, 2019 3:33 PM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Yes, you can fax it to: 202-564-9490.

Thanks,

-Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Tuesday, December 10, 2019 3:27 PM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

Darrell,

I just realized that I can't start forms for this one through CDX and the primary authorized official is not in to start one for me currently. Can I fax our response to you for this one? We will upload via CDX as well as soon as possible, but want to get this to you ASAP.

Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Monday, December 9, 2019 2:35 PM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Yes, the target organ is the lungs in this case.

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Monday, December 9, 2019 12:30 PM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

Darrell,

We have also had a question as to what 'target organ' toxicity refers to. Is this lungs, or a different organ?

Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Monday, December 9, 2019 11:18 AM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Yes, please submit it through CDX so we have an official record of the information.

Thanks,
-Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Monday, December 9, 2019 11:15 AM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

Would it help if I sent more info about the lack of sensitization?

Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Monday, December 9, 2019 10:55 AM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Peter,

Thanks for the feedback, I'm going to bring this case back to Options tomorrow and see what they say. I will let you know after the meeting.

Thanks,
-Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Monday, December 9, 2019 10:29 AM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

Darrell,

This is good news, but the client will find the 'respiratory sensitization' language unacceptable. That would essentially be reclassifying an existing substance that they produce millions of kg a year as a respiratory sensitizer. These has been produced at their facility for decades and there is just no evidence that either causes sensitization issues. We have provided evidence that the substance is not a sensitizer, including the

actual OSHA listing for grain dusts, which does not include either canola or flax as allergens or sensitizers.

If you would like, I will speak with the toxicologist about this, but we are firm that this is not a sensitizer in any way.

Peter

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From: Stanley, Darrell <stanley.darrell@epa.gov>
Sent: Monday, December 9, 2019 9:55 AM
To: Peter Ranslow <pranslow@cermonline.com>
Subject: RE: PMN-xx-xx32/3

Hi Peter,

I have received the final Human Health risk assessment from RAD and based on the revised exposure estimates, there are no longer any inhalation risks for workers or the general population.

In order to complete this case, we are requesting that you update the SDSs for both cases with the following Hazard language:

"Section 15 - Regulatory information:
Based on EPA's assessment, this substance may cause skin irritation, eye irritation, respiratory sensitization, and specific target organ toxicity."

Once you have made the updates, please upload the new document through CDX (and alert me by email or phone). We won't be able to issue the final determination until we have the updated SDS.

Let me know if you have any questions.

Thanks,
-Darrell

From: Peter Ranslow <pranslow@cermonline.com>
Sent: Thursday, December 5, 2019 10:43 AM
To: Stanley, Darrell <stanley.darrell@epa.gov>
Subject: RE: PMN-xx-xx32/3

I approve the suspension. I called Greg and hopefully he will get back with me soon.

Peter

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